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PATENT  
Customer No. 22,582  
Attorney Docket No. 05394.0011



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of )  
Stewart COLE et al. )  
Serial No. 09/673,476 ) Group Art Unit: 1634  
Filed: November 30, 2000 ) Examiner: A. Chakrabarti

For: A METHOD FOR ISOLATING A POLYNUCLEOTIDE OF INTEREST FROM THE  
GENOME OF A MYCOBACTERIUM USING A BAC-BASED DNA LIBRARY,  
APPLICATION TO THE DETECTION OF MYCOBACTERIA

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

**SUPPLEMENTAL RESPONSE TO RESTRICTION REQUIREMENT**

In response to an Office Action dated December 17, 2002 (Paper No. 15), and  
pursuant to 37 C.F.R. § 1.111, applicants submit the following amendments and  
remarks.

**IN THE CLAIMS:**

Please cancel claims 1-10, 12, 14-50 without prejudice or disclaimer.

Please amend the claims as follows:

11. (Amended) A purified polynucleotide, comprising an Open Reading Frame  
contained within SEQ ID NO:1, wherein the polynucleotide is selected from:

(a) nucleotide 1,695,944 through nucleotide 1,696,441 of the *Mycobacterium*

*tuberculosis* chromosome;

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(b) nucleotide 1,696,728 through nucleotide 1,697,420 of the *Mycobacterium tuberculosis* chromosome;

(c) nucleotide 1,698,096 through nucleotide 1,699,892 of the *Mycobacterium tuberculosis* chromosome;

(d) nucleotide 1,700,210 through nucleotide 1,701,088 of the *Mycobacterium tuberculosis* chromosome;

(e) nucleotide 1,701,293 through nucleotide 1,702,588 of the *Mycobacterium tuberculosis* chromosome;

(f) nucleotide 1,703,072 through nucleotide 1,704,091 of the *Mycobacterium tuberculosis* chromosome;

(g) nucleotide 1,704,091 through nucleotide 1,705,056 of the *Mycobacterium tuberculosis* chromosome;

(h) nucleotide 1,705,056 through nucleotide 1,705,784 of the *Mycobacterium tuberculosis* chromosome;

(i) nucleotide 1,705,808 through nucleotide 1,706,593 of the *Mycobacterium tuberculosis* chromosome;

(j) nucleotide 1,706,631 through nucleotide 1,707,524 of the *Mycobacterium tuberculosis* chromosome; or

(k) nucleotide 1,707,530 through nucleotide 1,708,648 of the *Mycobacterium tuberculosis* chromosome.

13. (Amended) A purified polynucleotide selected from:

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- a) a polynucleotide comprising at least 8 consecutive nucleotides of SEQ ID NO:1, wherein the polynucleotide is present in the genome of *M. tuberculosis* but absent from the genome of *M. bovis*;
- b) a polynucleotide having a sequence fully complementary to SEQ ID NO:1;  
and
- c) a polynucleotide that hybridizes under stringent hybridization conditions with the polynucleotide defined in a) or with the polynucleotide defined in b).

Please add the following new claims.

--51. (NEW) The polynucleotide of claim 13, wherein the stringent hybridization conditions comprise a hybridization step at 65°C in 6X SSC buffer, 5X Denhardt's solution, 0.5% SDS, and 100 µg/ml of salmon sperm DNA, two five minute washing steps at 65°C in 2X SSC and 0.1% SDS buffer, a 30 minute washing step at 65°C in 2X SSC and 0.1% SDS buffer, and a ten minute washing step at 65°C in 0.1X SSC and 0.1% SDS buffer .

52. (NEW) A purified polypeptide encoded by the polynucleotide of claim 11--.

#### REMARKS

Applicants respectfully request reconsideration and further examination in view of the following remarks.

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Paper No. 15 indicated that the response filed December 2, 2002, was not fully responsive to the previous Office Action because it did not include a clean copy of the amended claims. Applicants submit this supplemental paper, which includes a clean copy of the amended claims.

Claims 11, 13, and 51-52 are pending in this application. Claims 1-10, 12, and 14-50 have been canceled without prejudice or disclaimer. Claims 11 and 13 have been amended. Support for the amendment to claim 11 can be found in the substitute specification, including, for example, at page 13, ¶¶ [086]-[097] and at page 37, ¶ [0257]. Support for the amendment to claim 13 can be found in the substitute specification, including, for example, at page 11, ¶¶ [066], [070], and at page 12, ¶¶ [073]-[076].

Claims 51 and 52 have been added. Support for claim 51 can be found in the substitute specification, including for example at page 12, ¶¶ [077]-[083]. Support for claim 52 can be found in the substitute specification, including for example at page 10, ¶ [064], at page 11, ¶ [072] and at page 13, ¶¶ [086]-[097].

Thus, this amendment does not introduce any new matter into the specification.

In Paper No. 12, the Examiner required restriction under 35 U.S.C. § 121 to one of the following groups of claims:

- Group I - Claims 1-10, drawn to method of isolating nucleic acids;
- Group II - Claims 11-30, 38-42, 44, 45, 50-51, and 53, drawn to nucleic acids; and

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Group III - Claims 31-37, 43, 46-49, and 52 drawn to nucleic acid hybridization.

Applicants provisionally elect to prosecute Group II, claims 11, 13, and newly added claims 51-52 without traverse. Claims 11, 13, and 51 are drawn to nucleic acids, and claim 52 is drawn to polypeptides encoded by the nucleic acids of claim 11.

If there is any fee due in connection with the filing of this paper, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: January 23, 2003

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## APPENDIX

### IN THE CLAIMS:

Please cancel claims 1-10, 12, 14-50 without prejudice or disclaimer.

Please amend the claims as follows:

11. (Amended) [The] A purified polynucleotide, comprising an [of claim 10 which contains at least one] Open Reading Frame [(ORF)] contained within SEQ ID NO:1, wherein the polynucleotide is selected from:

(a) nucleotide 1,695,944 through nucleotide 1,696,441 of the *Mycobacterium tuberculosis* chromosome;

(b) nucleotide 1,696,728 through nucleotide 1,697,420 of the *Mycobacterium tuberculosis* chromosome;

(c) nucleotide 1,698,096 through nucleotide 1,699,892 of the *Mycobacterium tuberculosis* chromosome;

(d) nucleotide 1,700,210 through nucleotide 1,701,088 of the *Mycobacterium tuberculosis* chromosome;

(e) nucleotide 1,701,293 through nucleotide 1,702,588 of the *Mycobacterium tuberculosis* chromosome;

(f) nucleotide 1,703,072 through nucleotide 1,704,091 of the *Mycobacterium tuberculosis* chromosome;

(g) nucleotide 1,704,091 through nucleotide 1,705,056 of the *Mycobacterium tuberculosis* chromosome;

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(h) nucleotide 1,705,056 through nucleotide 1,705,784 of the *Mycobacterium tuberculosis* chromosome;

(i) nucleotide 1,705,808 through nucleotide 1,706,593 of the *Mycobacterium tuberculosis* chromosome;

(j) nucleotide 1,706,631 through nucleotide 1,707,524 of the *Mycobacterium tuberculosis* chromosome; or

(k) nucleotide 1,707,530 through nucleotide 1,708,648 of the *Mycobacterium tuberculosis* chromosome.

13. (Amended) [The] A purified polynucleotide [of claim 11, wherein said polynucleotide is] selected from [the group consisting of]:

a) a polynucleotide comprising at least 8 consecutive nucleotides of SEQ ID NO:1, wherein the polynucleotide is present in the genome of *M. tuberculosis* but absent from the genome of *M. bovis*;

b) a polynucleotide having a sequence fully complementary to SEQ ID NO:1;  
and

c) a polynucleotide that hybridizes under stringent hybridization conditions with the polynucleotide defined in a) or with the polynucleotide defined in b).

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